## REMARKS

Favorable reconsideration of this application is requested.

Claims 1, 3, 5, 7, 9, 11, 13-15 and 17-24 are in the case.

Claims 1, 3, 5, 7, 9, 11, 13 and 15 stand withdrawn from consideration as not reading on the elected invention.

It is again requested that these non-elected claims be rejoined with the elected claims upon allowance of the latter. Note MPEP §821.04.

The elected claims are Claims 17-24.

The Examiner has withdrawn the finality of the Official Action of July 27, 1998, now rejecting the claims under 35 U.S.C. §102(b) as being anticipated by DeHaan, and under 35 U.S.C. §103(a) as being unpatentable over Mueller, Seth and EP '596.

It is submitted that these are not viable rejections, particularly in view of the amendment to the claims.

The invention relates to an oral or dermal composition containing a pharmaceutical active substance and a thermoplastic coating and binding agent prepared by a method of applying a thermoplastic coating and binding agent in a hot-melt liquid state at a temperature of 100-150°C to said oral or dermal medicinal composition, followed by cooling to solidify the thermoplastic coating and binding agent, wherein said thermoplastic coating and binding agent consists essentially of a non-homogeneous mixture of, based on 100% by weigh of A and B:

A) 5-95% of a thermoplastic acrylic plastic with a melting temperature above room temperature and below 200°C, a glass transition temperature below 120°C, and a melt viscosity of 1,000 to 1,000,000 Pa-sec at the melting temperature; and

B) 95-5 wt.% of a flow improver, which, at room temperature, is not compatible with the thermoplastic acrylic plastic, has a melting temperature above room temperature but below 200°C, a weight average molecular weight under 20,000 d, and a melt viscosity below 100 Pa·sec at the melting temperature of the acrylic plastic.

Essential to the claimed invention is that components A and B form a non-homogeneous mixture, i.e., components A and B are not compatible, that the mixture consists essentially of components A and B, and that the composition has been obtained by applying the thermoplastic coating and binding agent in a hot-melt at a temperature of 100 to 150°C. Such clearly is not the case in any of the references now relied upon by the Examiner.

Specifically, with regard to the rejection of the claims for anticipation under 35 U.S.C. §102(b) by DeHaan, no hot-melt application clearly is disclosed by this reference. As so disclosed by DeHaan in its Example 1 referred to by the Examiner, the restraining phase was obtained from a solution of the components in chloroform, the housing phase was obtained from a powder mixture heated to 90°C until granuable, the mixture of the restraining phase and housing phase then being compacted. Such clearly does not involve a hot-melt extrusion at a temperature of 100-150°C, as claimed. Note that the restraining phase is obtained from a solution of "Eudragit" in chloroform, chloroform having a boiling point of 61°C, heating to only 90°C is disclosed for the preparation of the housing phase, and no heat is applied during compaction of the restraining phase and housing phase mixture. It is thus readily apparent that anticipation, within the meaning of 35 U.S.C. §102 requiring complete identity in the prior art, is not present.

Accordingly, withdrawal of the rejection of the claims under 35 U.S.C. §102 over DeHaan is requested.

With regard to the rejection of the claims under 35 U.S.C. §103(a) over the cited references, they also do not make obvious the claimed invention.

With regard to Mueller essential to its invention is that its pharmaceutical sustained-release composition contain its defined component b) in addition to defined components a) and c). The presence of component b) essential in the invention of Mueller, however, is precluded by the "consisting essentially of" language of the claims. Note the Examiner's acknowledgment to this effect with regard to his withdrawal of the rejection of the claims over the Canadian Patent 2,082,573 at page 2 of the Official Action of July 27, 1998. Consequently, even if component c) of the reference assertedly reads on claimed component B, the claimed invention is not made obvious thereby. Rather, Mueller quite evidently teaches away from Applicants' discovery. Moreover, and in any event, the claimed limitation with regard to incompatibility also is not so disclosed by Mueller, nor obvious therefrom.

As to Seth, under GENERAL PREPARATION INSTRUCTIONS at column 9, lines 29-41, it is disclosed that:

> The nonionic surfactant or mixture of such surfactants is taken in a vessel which can be heated and is brought to the molten state by heating to about 50°C. The organic polymer is added to the molten mass and the mixture is stirred until the organic polymer has dissolved completely or until a uniform suspension has formed. The active ingredient is then added, the mixture is stirred until a uniform suspension has formed and any air included is removed by leaving the composition to stand in a vacuum chamber. All the process measures are carried out at a temperature of about 50°C. Finally, hard gelatin capsules are filled with the calculated amount of the resulting composition.

It is thus readily apparent that no hot-melt application at a temperature of 100-150°C is involved in Seth, nor is a non-homogenous mixture obtained therein. Rather, contrariwise, the conditions of Seth are such so as to obtain a uniform mixture.

With regard to the European patent, similarly, in the preparation of its homogeneous composition, not a non-homogeneous mixture as claimed, a temperature of 65°C is used. Note its examples.

Further, in the European patent the excipients are selected in such a way that they exert a dissolving or gelling effect and a lubricating effect on the polymer. By using such excipients a homogeneous mixture is formed which is compatible even after solidification due to the dissolving or gelling effect of the excipients. A solidified composition obtained from the melt thus remains soft and sticky on its surface, not being suitable as a medicinal form surface. This is not the case in the claimed invention where the defined components A and B are heated to a temperature of 100-150°C and are so selected that their combination provides for an incompatible, nonhomogeneous mixture upon solidification. This clearly is against the express requirement of the reference.

Specifically, when a nonhomogeneous mixture would be obtained by using an excipient selected from the classes of materials disclosed by the European patent, such excipient would not be useful for attaining patentee's objective. Note that homogeneity depends not only on the requisite selection of a particular excipient, but also in combining such selected excipient with a particular polymer and at a specified temperature. Thus, while in Example 17 of the European patent referred to by the Examiner a polymer within the scope of the claims is present, nevertheless, only a specific excipient is illustrated as being combinable therewith, such specific excipient, however, providing for a homogeneous mixture wherein the excipient has a plasticizing effect to dissolve or gel the polymer which does not separate upon cooling due to the dissolving or gelling effect and not having been heated to the requisite temperature. In the claimed invention, on the other hand, contrariwise,

the selected combination of components and heating must be such so as to obtain an incompatible, nonhomogeneous mixture of the components upon cooling. Such selection and condition clearly are contraindicated and not inherent in the European patent, it manifestly teaching away therefrom.

Withdrawal of the rejection of the claims under 35 U.S.C. §103 thus is requested.

It is submitted that the claims define a patentable invention. Their allowance is solicited.

Respectfully submitted,

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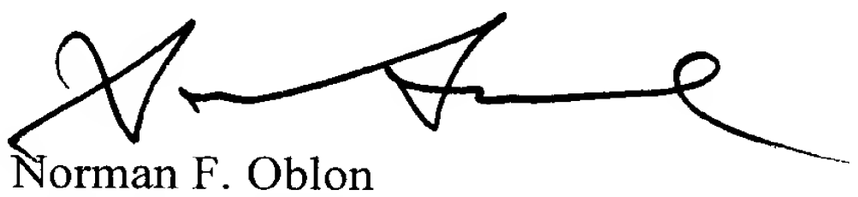

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